

This draft has not been adopted or endorsed by the European Commission. Any views expressed are the preliminary views of the Commission services and may not in any circumstances be regarded as stating an official position of the Commission. The information transmitted is intended only for the Member State or entity to which it is addressed for discussions and may contain confidential and/or privileged material.

COMMISSION IMPLEMENTING REGULATION (EU) .../...

of **XXX**

authorising the placing on the market of *Rhizomucor pusillus* biomass powder as a novel food and amending Implementing Regulation (EU) 2017/2470

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2015/2283 of the European Parliament and of the Council of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001¹, and in particular Article 12(1) thereof,

Whereas:

- (1) Regulation (EU) 2015/2283 provides that only novel foods authorised and included in the Union list of novel foods may be placed on the market within the Union.
- (2) Pursuant to Article 8 of Regulation (EU) 2015/2283, Commission Implementing Regulation (EU) 2017/2470² has established a Union list of novel foods.
- (3) On 16 May 2020, the company The Protein Brewery B.V. ('the applicant') submitted an application for an authorisation to the Commission in accordance with Article 10(1) of Regulation (EU) 2015/2283 to place *Rhizomucor pusillus* biomass powder on the Union market as a novel food. The applicant requested for the *Rhizomucor pusillus* biomass powder to be used as a whole food, as an ingredient in several food products, including meal replacement for weight control at levels not exceeding 40 g per meal, and in food supplements as defined in Directive 2002/46/EC of the European Parliament and of the Council³, at levels not exceeding 6g/day for the general adult population, excluding pregnant and lactating women.

¹ OJ L 327, 11.12.2015, p. 1. ELI: <http://data.europa.eu/eli/reg/2015/2283/oj>

² Commission Implementing Regulation (EU) 2017/2470 of 20 December 2017 establishing the Union list of novel foods in accordance with Regulation (EU) 2015/2283 of the European Parliament and of the Council on novel foods (OJ L 351, 30.12.2017, p. 72, ELI: http://data.europa.eu/eli/reg_impl/2017/2470/oj).

³ Directive 2002/46/EC of the European Parliament and of the Council of 10 June 2002 on the approximation of the laws of the Member States relating to food supplements (OJ L 183, 12.7.2002, p. 51, ELI: <http://data.europa.eu/eli/dir/2002/46/oj>).

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- (4) On 16 May 2020, the applicant also made a request to the Commission for the protection of the proprietary scientific studies and data, namely, identity of the novel food⁴, production process⁵, compositional analysis⁶, history of use⁷, absorption, distribution, metabolism and excretion information⁸, nutritional information⁹, toxicological information¹⁰, genotoxicity¹¹, subchronic toxicity study¹², human data¹³, and allergenicity¹⁴.
- (5) On 7 January 2021, the Commission, requested the European Food Safety Authority ('the Authority') to carry out an assessment of *Rhizomucor pusillus* biomass powder as a novel food.
- (6) On 29 September 2025, the Authority adopted its scientific opinion "Safety of *Rhizomucor pusillus* biomass powder as a novel food pursuant to Regulation (EU) 2015/2283¹⁵" in accordance with Article 11 of Regulation (EU) 2015/2283.
- (7) In its scientific opinion, the Authority concluded that *Rhizomucor pusillus* biomass powder is safe under the proposed conditions of use for the proposed target population. Therefore, that scientific opinion gives sufficient grounds to establish that *Rhizomucor pusillus* biomass powder, when used as a whole food, as an ingredient in food products, including , meal replacement for weight control at levels not exceeding 40 g per meal, and in food supplements at levels not exceeding 6g/day for the general adult population, excluding pregnant and lactating women, fulfils the conditions for its placing on the market in accordance with Article 12(1) of Regulation (EU) 2015/2283.
- (8) In its scientific opinion, the Authority also noted that its conclusion on the safety of the novel food was based on analytical reports for the production process,

⁴ Annex 2.2.3 – Identity of the NF_conf.pdf; 2.2.3_Identity of the novel food_updated_June2025.pdf; 2.2.3_Appendix C1_conf.pdf; 2.2.3_Appendix C2_conf.pdf; 2.2.3_Appendix C3_conf.pdf; 2.2.3_Appendix C5_conf.pdf to 2.2.3_Appendix C8_conf.pdf.

⁵ Annex 2.3.1 – Production process_conf.pdf; 2.3.1_Appendix D1_updated.pdf; 2.3.1_Appendix D_conf.pdf; Answer to EFSA question 2_19042022.pdf.

⁶ 2.4.3. Compositional data_conf_updated_June 2025.pdf; 2.4.4_Stability_updated Aug 2025.pdf.

⁷ 2.6_History of use_updated.pdf; 2.6_Appendix A_conf.pdf; 2.6_Appendix C_conf.pdf; 2.6_Appendix D_conf.pdf.

⁸ 2.8_ADME_updated.pdf; 2.8_Appendix A_conf.pdf.

⁹ 2.9_Nutritional information_updated_Aug 2025.pdf.

¹⁰ 2.10.1_General considerations_updated sept.pdf; 2.10.7.2 Specific cases microorganisms_updated.pdf; 2.10.7.2_Appendix A1_updated_05082024.pdf; 2.10.7.2_Appendix D1_conf.pdf; 2.10.7.2_BioIT BiomaX 2018 Rh pusillus_conf.pdf.pdf; 2.10.7.2_Mycotoxin overview_supplying_conf.pdf; 2.10.7.2_NGS report Baseclear Rh pusillus_conf.pdf; 2.10.7.2_WGS BaseClear description_conf.pdf.

¹¹ 2.10.2_Genotoxicity_updated May 2025.pdf; HCD Ames 2021.pdf; 2.10.2_Appendix D5.pdf; Answer to EFSA question 13_22112024.pdf; 2.10.2_Appendix D7.pdf; 2.10.2_Appendix D8.pdf.

¹² 2.10.3_Subchronic toxicity_updated.pdf; 2.10.3_Appendix D1.pdf; Answers to EFSA question 14_19042022.pdf.

¹³ 2.10.6_Human data_Updated.pdf; 2.10.6_Appendix D_datap (1).pdf; Hb values TOMMY study.xlsx.

¹⁴ 2.11_Allergenicity_updated.pdf; 2.11_Appendix A_updated.pdf; 2.11_Appendix D1_updated.pdf; 2.11_Appendix D2_conf.pdf; 2.11_Appendix D3_SampleN1_Results.xlsx; 2.11_Appendix D3_SampleN3_Results.xlsx; 2.11_Appendix D3_updated.pdf; 2.11_Appendix D4.pdf; 2.11_In silico homology search_updated.xlsx; Answers to EFSA questions 15 and 16.pdf; Proteome Factory_Study Report_05062020.pdf.

¹⁵ EFSA Journal. 2025;23:e9707 (<https://doi.org/10.2903/j.efsa.2025.9707>)

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compositional analysis, genotoxicity, subchronic toxicity study and allergenicity, without which it could not have assessed the novel food and reached its conclusion.

- (9) The applicant declared that they held proprietary and exclusive rights of reference to the scientific studies and data at the time they submitted the application.
- (10) The Commission assessed all the information provided by the applicant and considered that they have sufficiently substantiated the fulfilment of the requirements laid down in Article 26(2) of Regulation (EU) 2015/2283. Therefore, the scientific evidence and data, namely, production process, compositional analysis, genotoxicity, subchronic toxicity study, and allergenicity should be protected in accordance with Article 27(1) of Regulation (EU) 2015/2283. Accordingly, only the applicant should be authorised to place *Rhizomucor pusillus* biomass powder on the market within the Union during a period of five years from the entry into force of this Regulation.
- (11) However, restricting the authorisation of *Rhizomucor pusillus* biomass powder and the reference to the scientific evidence and data contained in the applicant's file for the sole use by them does not prevent subsequent applicants from applying for an authorisation to place on the market the same novel food provided that their application is based on legally obtained information supporting such an authorisation.
- (12) Directive 2002/46/EC of the European Parliament and of the Council lays down requirements on food supplements. The use of *Rhizomucor pusillus* biomass powder should be authorised without prejudice to that Directive.
- (13) It is appropriate that the inclusion of *Rhizomucor pusillus* biomass powder as a novel food in the Union list of novel foods contains the information referred to in Article 9(3) of Regulation (EU) 2015/2283.
- (14) *Rhizomucor pusillus* biomass powder should be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470. The Annex to Implementing Regulation (EU) 2017/2470 should therefore be amended accordingly.
- (15) The measures provided for in this Regulation are in accordance with the opinion of the Standing Committee on Plants, Animals, Food and Feed,

HAS ADOPTED THIS REGULATION:

Article 1

1. *Rhizomucor pusillus* biomass powder is authorised to be placed on the market within the Union.

Rhizomucor pusillus biomass powder shall be included in the Union list of novel foods set out in Implementing Regulation (EU) 2017/2470.

2. The Annex to Implementing Regulation (EU) 2017/2470 is amended in accordance with the Annex to this Regulation.

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Article 2

Only the company The Protein Brewery B.V.¹⁶ is authorised to place on the market within the Union the novel food referred to in Article 1, for a period of five years from [*the date of entry into force of this Regulation*] [*OP please insert the date*], unless a subsequent applicant obtains an authorisation for that novel food without reference to the scientific data protected pursuant to Article 3 or with the agreement of The Protein Brewery B.V.

Article 3

The scientific data contained in the application file and fulfilling the conditions laid down in Article 26(2) of Regulation (EU) 2015/2283 shall not be used for the benefit of a subsequent applicant for a period of five years from the date of entry into force of this Regulation without the agreement of The Protein Brewery B.V.

Article 4

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

*For the Commission
The President*

¹⁶ Goeseelsstraat 10, 4817 MV, Breda, Netherlands.